Manual data entry in OpenClinica

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1. User Support Information

A study in OpenClinica is coordinated centrally by a study coordinator or study manager. Please contact your study management / study coordinator if you have any questions about the study or about working in OpenClinica (e.g. entering data, monitoring data, signing completed CRFs).
If necessary, the study management / study coordinator will contact the OpenClinica administrator.

How to protect subject's privacy

Do not enter any identifying information about study subjects in OpenClinica. The following type of information is considered identifying and should not be entered in OpenClinica: Subject's name, initials, ZIS/hospital number, BSN.
NB: date of birth is not allowed for studies that started after February 2014 unless measures are taken that are required by law (Wet bescherming persoonsgegevens).
Also mind that you do not enter identifying information in free text fields (such as fields to enter comments).

2. Getting started in OpenClinica

2a. Account Procedure

If you want to enter data in the eCRF for a study you need to have a user account in OpenClinica.

OpenClinica Account Procedure

1. Please send a request for user account to the study management / study coordinator.
   a. Fill in your hospital name, your role in the study, name and e-mail address
   b. Indicate the requested user role at site level
2. Study management / study coordinator will send the account request to the OpenClinica administrator via TraIT Topdesk
3. The account information will be sent to you by e-mail (sender is servicedesk@ctmm-trait.nl)

2b. User Roles applicable for site personnel

There are four study roles at site level; It is recommended to let your OpenClinica study role correspond to the tasks delegated by the Principal Investigator on the Delegated Task List.

Possible User Roles at Site level:
a) **Investigator** (data entry & signature)
b) **Monitor** (verification of entered data)
c) **Clinical Research Coordinator** (data entry)
d) **Data Entry Person** (data entry)

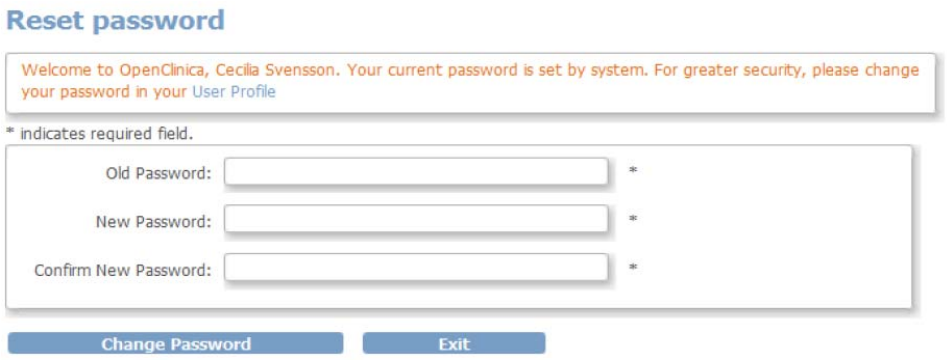
2c. Log in to OpenClinica

- Open the internet browser
  OpenClinica kan benaderd worden via Internet Explorer (versie 7 of hoger) en Firefox (versie 3 of hoger). **OpenClinica is niet compatible met Chrome en Safari.**
- Go to the following address: www.openclinica.nl
- Enter the user name and password as received by e-mail and click on 'Login'.

OpenClinica®
Community Edition
Login
User Name
lpijpers
Password
Login
Forgot Password?
News
11/03 - Growing the Community - A recent discussion on the OpenClinica users ...
10/12 - Clinical Trials in the Cloud (Part II) - The other day I posted an overview of the new ...
10/08 - Clinical Trials in the Cloud - I got a phone call the other day from a longtime ...
08/29 - New! OpenClinica 3.1 "Gap" Training - We are excited to announce a new course designed ...
More...

2d. Change password

The first time you login to OpenClinica, you will be asked to change your password. A password of 8 characters is required.


Reset password
Welcome to OpenClinica, Cecilia Svensson. Your current password is set by system. For greater security, please change your password in your User Profile
* indicates required field.
Old Password:
New Password:
Confirm New Password:
Change Password
Exit

2e. Log out to OpenClinica

When you are finished with data-entry you must log out. This prevents unauthorized persons from viewing or changing data. You log out by clicking on the link 'Log Out' in the upper right corner of the screen.

2f. Glossary of terms

Below the OpenClinica terms are explained that are used in this manual:

Study: In OpenClinica, a clinical trial or clinical research project, including all the metadata and data for it.

Sites: Locations where the Study is taking place. You can work with OpenClinica at the Site level, which limits the view of the Study to a specified Site.

Study Level: A view of the Study that aggregates information and data for all Sites in the Study.

User: Person using the OpenClinica software. A user can have one or more Roles in one or more Studies or Sites.

Roles: Categories for users in OpenClinica that determine the tasks available to them in the system.

Event: See Study Event.

Study Event: A visit or encounter in the Study where data is captured or created. A Study Event packages one or more case report forms (CRFs).

CRF (Case Report Form): A form that collects Study-related information for a Study Subject. CRFs are composed of Sections, Item Groups (multiplied via 'Add button' in CRF), and Items. CRFs can have multiple versions.

Subject Case Book: All CRFs for all Events for a Study Subject.

Subject Matrix: Overview of all subjects in the Study that are entered in OpenClinica in your center with the status of data entry.

Item: Also known as a data Item. A single question in a CRF. Items have metadata attached to them. Each Item has an Object Identifier (OID) attached to it. Items can have multiple Edit Checks attached to them.

Enrollment: Adding a Subject to a Study. The OpenClinica Enrollment Date is when the Subject is added to an OpenClinica Study.

Study Subject: A person added to a Study in OpenClinica. Also referred to as a Subject.

Study Subject ID: A unique identifier generated manually when adding a Subject to a Study.

Secondary ID: An optional identifier given to a Subject. Not to be used to register identifying information about the subject.

Remove: A remove action makes the information unavailable in the OpenClinica system. You can restore information that has been removed to make it available again. Most information in OpenClinica can only be removed and not deleted so that it can be restored if necessary. However, in some cases information can be deleted. See also the glossary description for Delete.

Delete: A delete action completely removes the information from the OpenClinica system. Deleted information cannot be restored, although the audit log tracks the deletion action.

Nearly all information in OpenClinica can be removed rather than deleted because removed information can be restored.

Discrepancy Notes: Means of communicating about CRF Items whose value, condition, level of detail, etc. are not as expected.

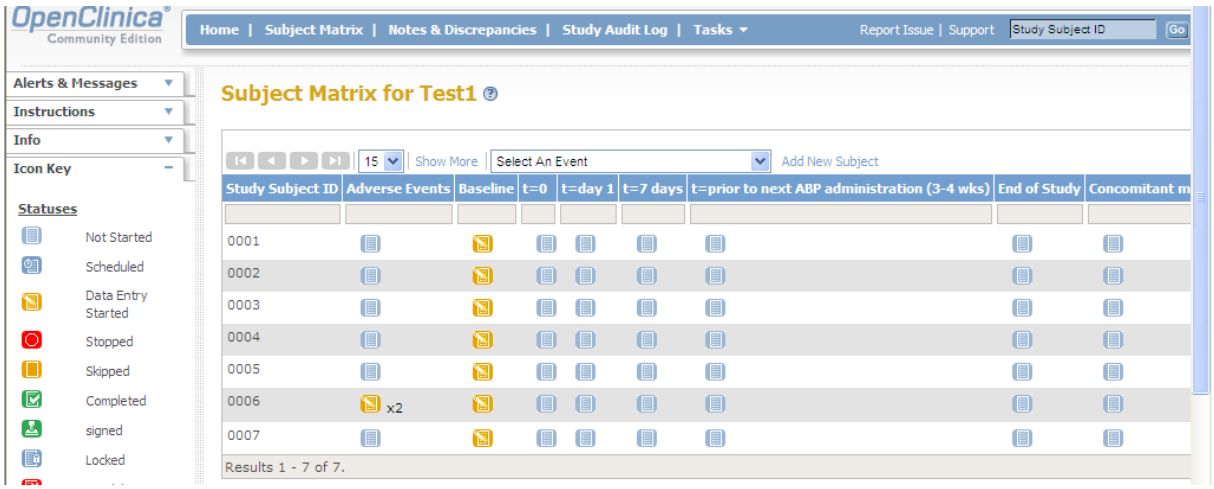
Audit Log: System feature that maintains a historical record of key actions related to a Study Subject that have run on the OpenClinica database.

3. OpenClinica Home Page

After logging in the home page will appear. This home page is the same for Investigators and Clinical Research Coordinators

This page shows the Subject Matrix which gives an overview of all subjects in the study that are entered in OpenClinica in your center (first column) and shows the status of data entry for the events (in the row to the right of the Study Subject ID).

This page also shows the Notes & Discrepancies that are assigned to you. This also will be explained in more detail later.



4. Required fields in OpenClinica

All fields that are indicated with an asterisk in OpenClinica are required fields and need to be completed.

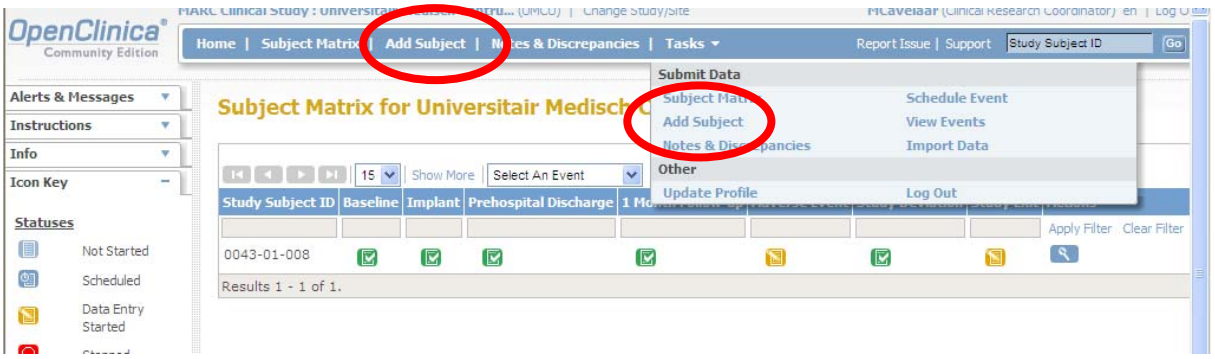
5. How to add a subject

Below a general explanation is given for data entry in OpenClinica:

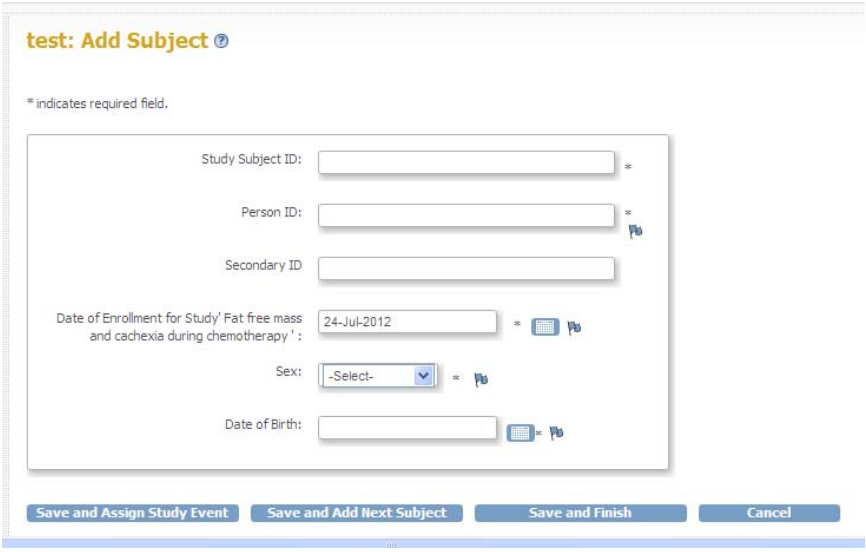
If you want to enter data for a new subject you need to:

- Add the new subject (explained on the next page)
- Schedule the event for which you want to enter data (explained on page 8, 6b)
- Open the CRF page for which you want to enter data (explained on page 9, 6c)

To **add a new subject** in OpenClinica, click on menu option 'Add Subject' or click on menu option 'Tasks' and then 'Add Subject' (see below for both options).



After clicking 'Add Subject' the next window will appear:



Depending on the setup of the study, some of the fields may not appear or may not be required to fill out (fields that are not marked with an asterisk can be left blank).

The Study Subject ID is always a required field. The study management / study coordinator will give you an instruction which Study Subject IDs and Person IDs (if required) should be used and which date needs to be chosen for "Date of Enrollment".

Now you can click on one of the four options:

If you do not want to proceed to schedule an event / enter data you can Click Save and Finish. Then you can proceed to enter data for that subject at a later time. You can add another subject by clicking on Save and Add Next Subject. When you click on Save and Assign Study Event you will **schedule the event**. (see 6b 'How to schedule an event').

6. How to submit data

6a. The status of a CRF and of an Event

An event can have different statuses. These are indicated by icons and these icons are used for Events and for CRFs:

Statuses			
	Not Started	event	CRF
	Scheduled	event	
	Data Entry Started	event	CRF
	Stopped	event (set manually)	
	Skipped	event (set manually)	
	Completed	event	CRF
	Signed	event (set manually)	
	Locked		CRF
	Invalid		CRF

Status of a CRF:

The status of a CRF can be:

- Not Started: (nothing has happened yet),
- Data Entry Started: (once you have opened the CRF but not necessarily entered data),
- Completed: (when you have marked CRF complete),
- Locked: (if a version of a CRF is archived, then the status of the CRFs that were already opened will change to Locked), and
- Invalid: (all CRFs for a subject that is removed).

Status of an Event:

The status of an Event changes in a similar way as status of a CRF, but it has more statuses. You can see these in the Subject Matrix:

- Not Started: If no date has been given for an Event
- Scheduled: If a start-date is given, but no data-entry has been performed yet
- Data Entry Started: If data-entry has started on one of the CRFs of the Event
- Completed: When all required CRFs of an Event are “Marked as Complete”
- Skipped: Sometimes a visit is skipped. In that case you can manually set the status to “Skipped”.
- Stopped: Under very rare circumstances data-entry of an Event will be stopped halfway. In that case you can manually set the status to “Stopped”.
- Signed: If the investigator has signed the event.

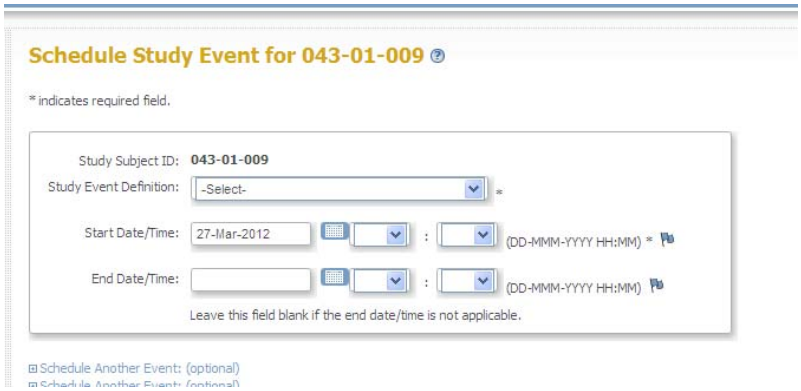
CRFs can be checked, using the source documents, the so called Source Data Verification or SDV. This is done by the Study team and it will not be visible to you by a change in icons.

6b. How to schedule an event

Before data can be entered for an event, the event needs to be scheduled in OpenClinica. This means that a Start Date/Time needs to be given. This is a system requirement and there is no meaning to this date for the user. Therefore, the default date (date of today) can be used. An End Date/Time is optional and should be left blank.

After you have added a subject in OpenClinica you can proceed to schedule an event / enter data by clicking Save and Assign Study Event (see below).

Now the next screen will open:


Schedule Study Event for 043-01-009
* indicates required field.
Study Subject ID: 043-01-009
Study Event Definition: -Select-
Start Date/Time: 27-Mar-2012 (DD-MMM-YYYY HH:MM) *
End Date/Time: (DD-MMM-YYYY HH:MM)
Leave this field blank if the end date/time is not applicable.
Schedule Another Event: (optional)

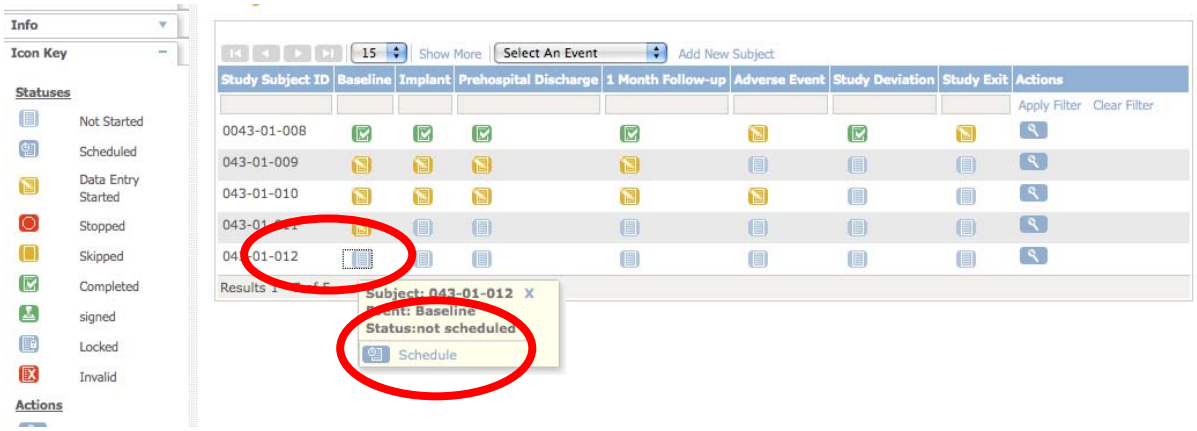
Select the Study Event for which you want to enter data via the select box (for example Baseline) and click on “Proceed to Enter Data”.

Note that by default the “Start Date/Time” will be pre-completed by the date of today; you do not need to change this date. The “End Date/Time” field can be left blank

After you have selected “proceed to enter data” the screen ‘enter or validate Data for CRFs’ will open (see on page 9 and 10).

For subjects that are already added in OpenClinica data can be entered from the subject matrix.

If a subject was added and no event was scheduled after this, the status of the event is: ‘not started’ . Now the event can be scheduled from the subject matrix. To do this, you click on the event that you want to schedule and click on schedule (see below).

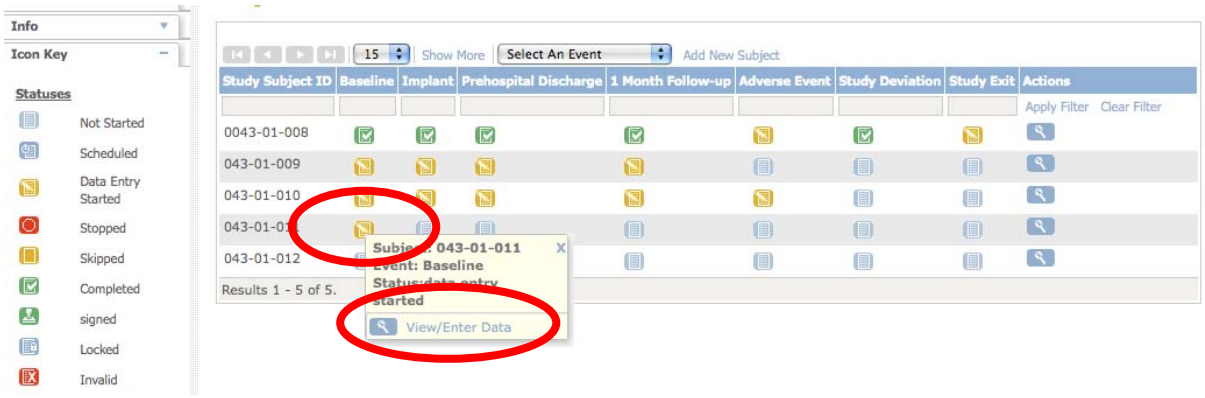


After this, you can schedule the event as explained on page 8, and click ‘Proceed to enter data’ .

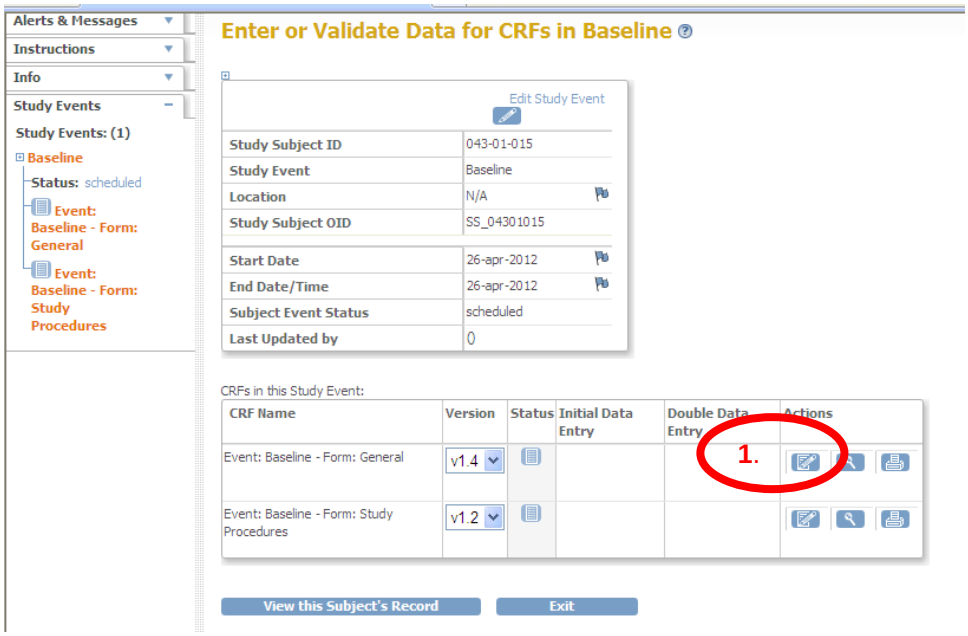
6c. How to enter data in CRF

If the event is already scheduled, the status of the event is: ‘scheduled’ .

You can enter data for events by clicking on the event (or) and then click on View/Enter Data (see below) in the floating window.

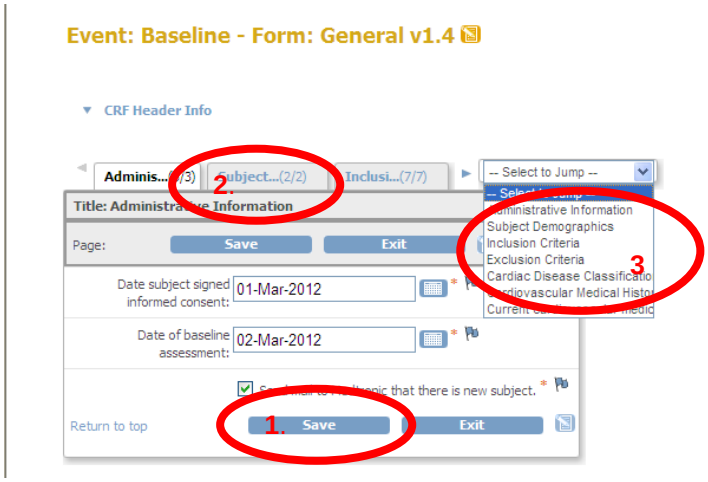


Now the screen ‘enter or validate Data for CRFs’ will open (see below). In this screen all CRF pages are listed that should be completed for the Baseline visit.



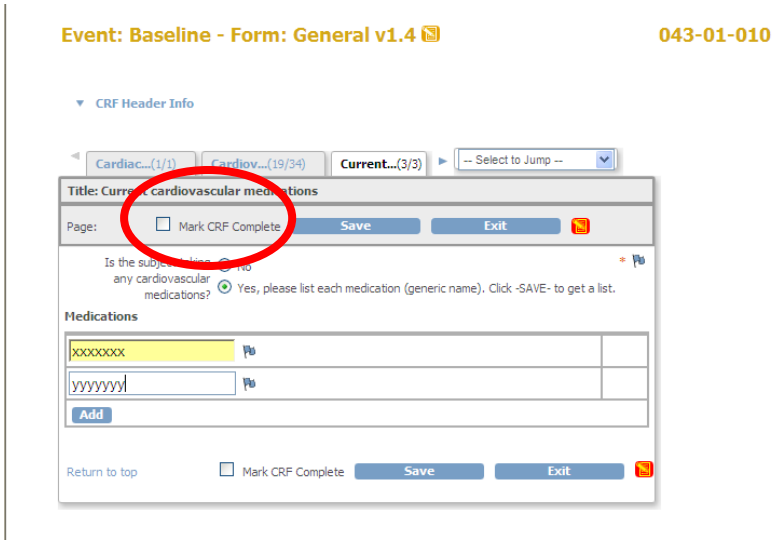
Click on the pencil icon to the right of the CRF name to start enter data in this CRF (see 1 above). This will **Open the CRF page** (see below).

Data can now be entered. A Date can be entered by clicking on the date picker. You can save the data by clicking on ‘Save’ (see 1 below). Navigate to the next section in the CRF via the tabs (see 2 below) or via “Select to jump” (see 3 below). Always click ‘Save’ before you go to the next section, unless you do not want to save the data.

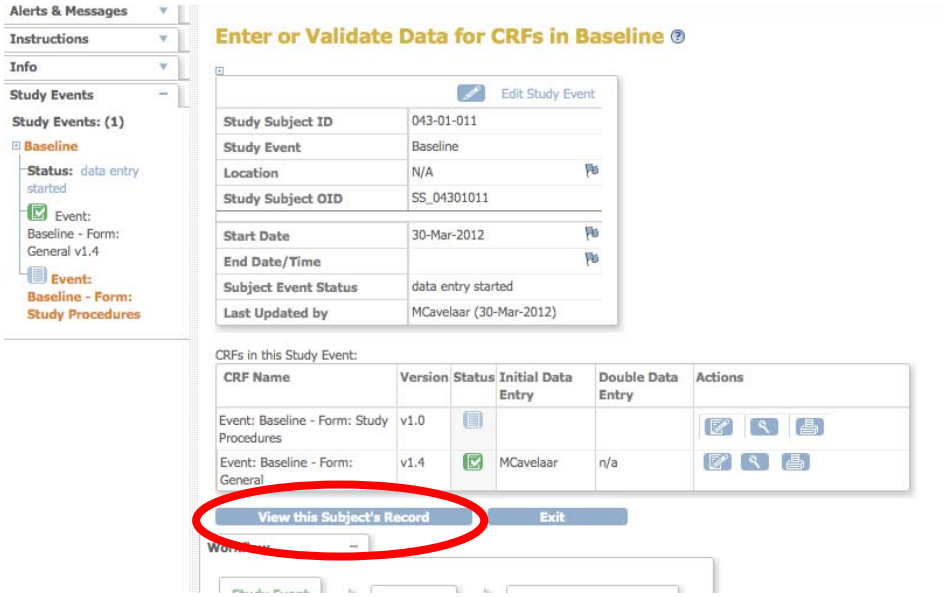


6d. How to mark CRF complete

If you think data are completely and correctly entered, you may click on ‘Mark CRF Complete’. You can do this in the last section of the CRF (see below).

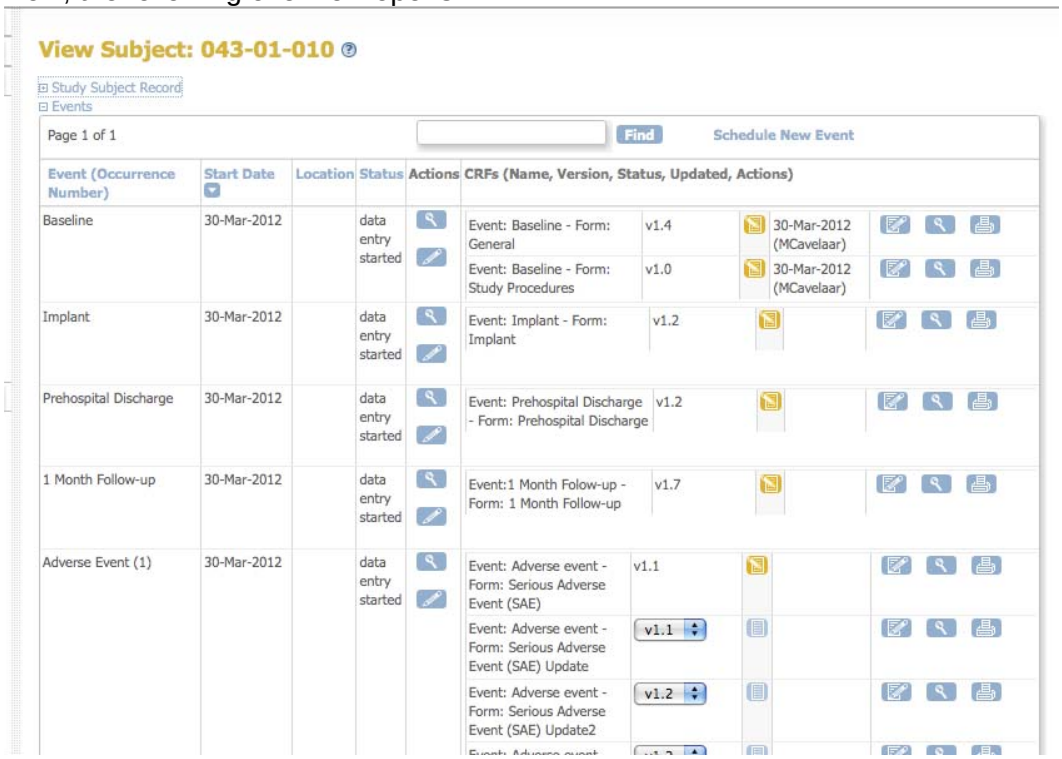


If you mark the CRF Complete the status of the CRF will change to “Completed” (see below). After entering and saving the data for this CRF the overview of CRFs that belong to this event will be shown again (also see below). The other CRF page(s) can be completed in the same way as the previously explained.


Alerts & Messages
Instructions
Info
Study Events
Study Events: (1)
Baseline
Status: data entry started
Event: Baseline - Form: General v1.4
Event: Baseline - Form: Study Procedures
Enter or Validate Data for CRFs in Baseline
Edit Study Event
Study Subject ID 043-01-011
Study Event Baseline
Location N/A
Study Subject OID SS_04301011
Start Date 30-Mar-2012
End Date/Time
Subject Event Status data entry started
Last Updated by MCavelaar (30-Mar-2012)
CRFs in this Study Event:
CRF Name | Version | Status | Initial Data Entry | Double Data Entry | Actions
Event: Baseline - Form: Study Procedures | v1.0
Event: Baseline - Form: General | v1.4 | MCavelaar | n/a
View this Subject's Record
Exit

From the 'enter or validate data for CRFs' window you can click on the 'View this Subject's Record' (see above) to get an overview of status of data entry for the events that are scheduled:

Now, the following overview opens:


View Subject: 043-01-010
Study Subject Record
Events
Page 1 of 1
Find
Schedule New Event
Event (Occurrence Number) | Start Date | Location | Status | Actions | CRFs (Name, Version, Status, Updated, Actions)
Baseline | 30-Mar-2012 | data entry started
Event: Baseline - Form: General v1.4 30-Mar-2012 (MCavelaar)
Event: Baseline - Form: Study Procedures v1.0 30-Mar-2012 (MCavelaar)
Implant | 30-Mar-2012 | data entry started
Event: Implant - Form: Implant v1.2
Prehospital Discharge | 30-Mar-2012 | data entry started
Event: Prehospital Discharge - Form: Prehospital Discharge v1.2
1 Month Follow-up | 30-Mar-2012 | data entry started
Event:1 Month Folow-up - Form: 1 Month Follow-up v1.7
Adverse Event (1) | 30-Mar-2012 | data entry started
Event: Adverse event - Form: Serious Adverse Event (SAE) v1.1
Event: Adverse event - Form: Serious Adverse Event (SAE) Update v1.1
Event: Adverse event - Form: Serious Adverse Event (SAE) Update2 v1.2

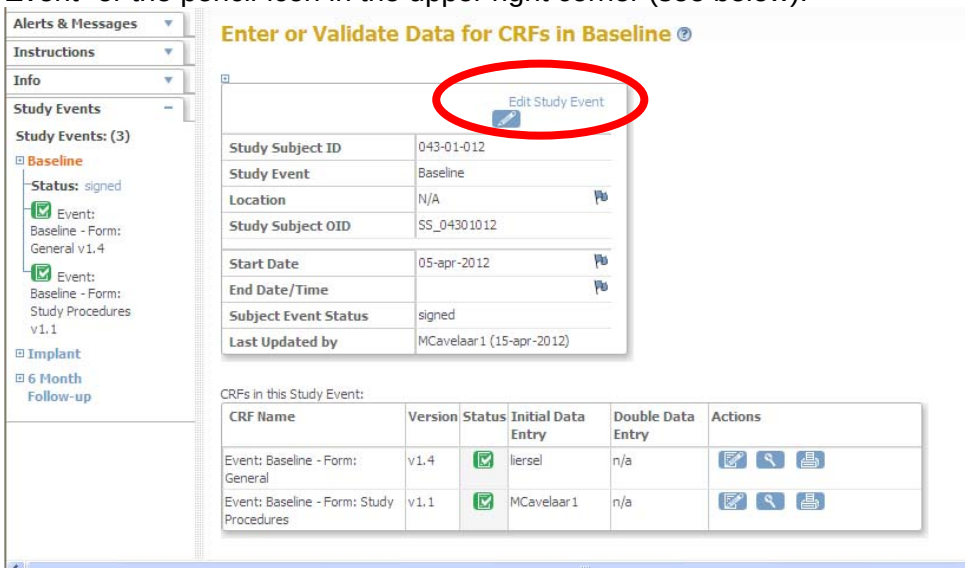
6e. How to change data that are previously entered

The procedure to change data is the same as entering data (explained on page 9/10):

Click on menu option ‘Subject Matrix’ and click on the event for which you want to change data and then click ‘View/Enter Data’.

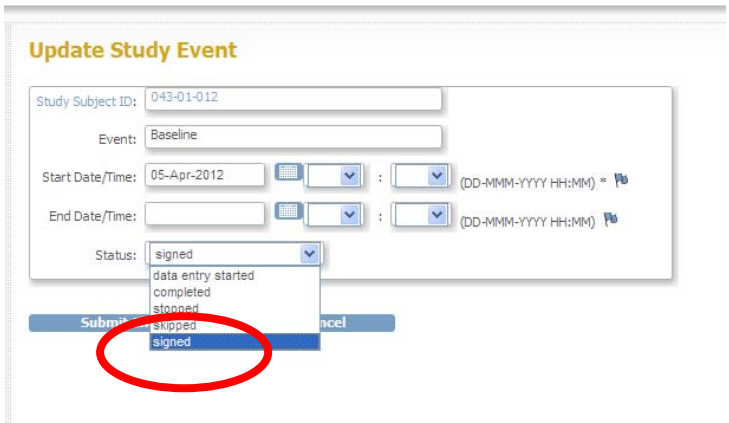
6f. How to set the status of an event including sign the CRF

To manually set the status of an Event you first schedule it, if you haven't already done so. In the Subject Matrix you click on the Event and in the floating window you click “View/Enter Data”. In the screen Enter or Validate Data for CRFs in [Event name] you click “Edit Study Event” or the pencil-icon in the upper right corner (see below).

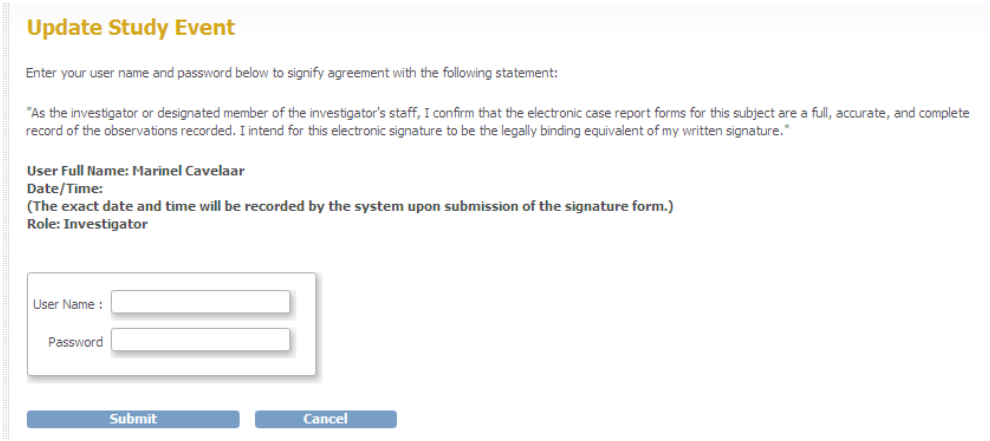


In the window that opens you can set the status of the Event to “Skipped” or “Stopped”.

The CRF can only be signed off by the investigator. To do this the investigator should manually set the status of the Event to “signed” (see below). This is only possible if all CRFs for this event are marked complete.



After “submit changes” is clicked the following window opens:


Update Study Event
Enter your user name and password below to signify agreement with the following statement:
"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."
User Full Name: Marinel Cavelaar
Date/Time:
(The exact date and time will be recorded by the system upon submission of the signature form.)
Role: Investigator
User Name :
Password
Submit
Cancel

Here the investigator should enter his/her user name and password and then click on "Submit". Now the status of the event will change to "signed".

7. Notes & Discrepancies

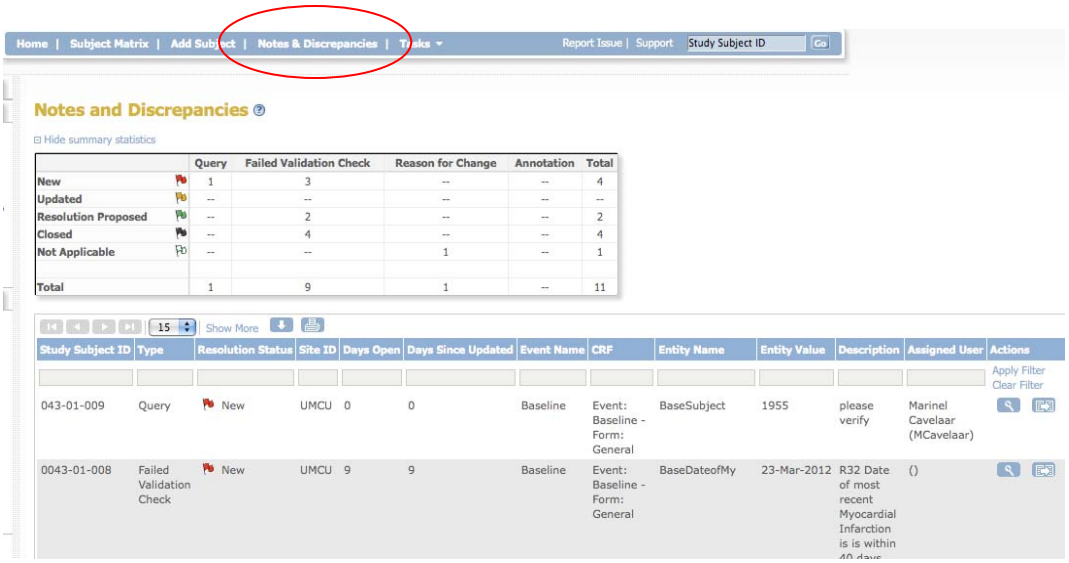
The OpenClinica Notes and Discrepancies module provides a means for users to document, communicate, and manage issues about data in the clinical study.

There are four different types of notes/discrepancies in OpenClinica:

1. Annotation: this is a comment to data that is given by the person who entered the data.
2. Failed Validation Check: this is an automatic query by the system that fires when a validation check fails
3. Query: This is a manual query that is put in to the system by the study team
4. Reason for Change: if the CRF is marked as completed ( ) the system will ask you to give a reason for change of the data.

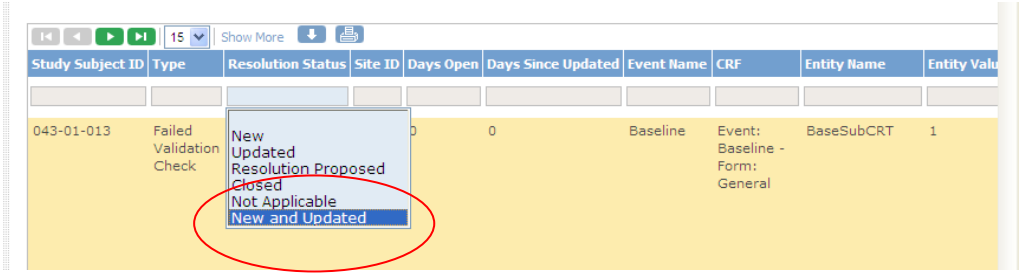
A Discrepancy has a status, which is indicated by the color of the flag: "New", "Updated", "Resolution Proposed", "Closed or "Not Applicable". The status indicates if an action is required and by whom. The status "Closed" and "Not Applicable" do not require any action. The status "Resolution Proposed" require an action by the monitor/study team. The status "New" and "Updated" require an action by the site entering data (i.e. clinical research coordinator and investigator).

You can get a list of all Discrepancies by clicking 'Notes & Discrepancies' in the top of your screen. In the screen that opens all Discrepancies are listed and a summary of this list is given in the top of the screen (see below).



The site entering data (i.e. the Clinical Research coordinator and the Investigator) should respond to the red and the yellow flags (New and Updated). Also, note the guideline regarding responses to these types of Discrepancy Notes (page 18).

In the overview you can filter on the status of the discrepancy (see below). Here you can select the option New and Updated for Resolution Status.



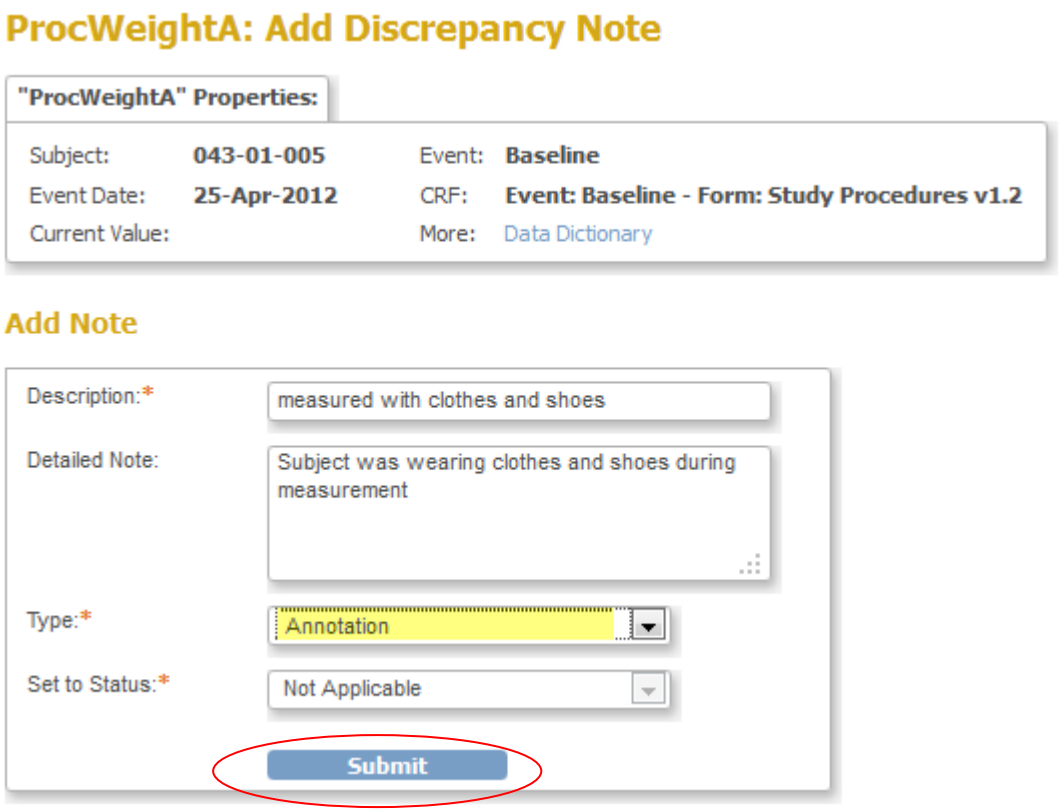
By clicking on the magnifier icon in the column ‘Actions’ you can directly open the discrepancy note and propose a resolution. By clicking on the icon you navigate to the CRF that contains the data field with the Discrepancy Note concerned. There you can click on the flag icon to open the discrepancy note and propose a resolution. By clicking on the icon the CRF will only open in view mode. Therefore, it is not possible to change the entered data in the CRF. For this you need to go to the CRF via the Subject Matrix.

A Discrepancy can be assigned to you. This is visible in the column ‘Assigned User’.

7a. Example of an Annotation

At any time you can add a comment to data you have entered by clicking on the blue flag icon next to the field. For example you want to add a comment to weight, click on the flag icon right to the item weight (see below)

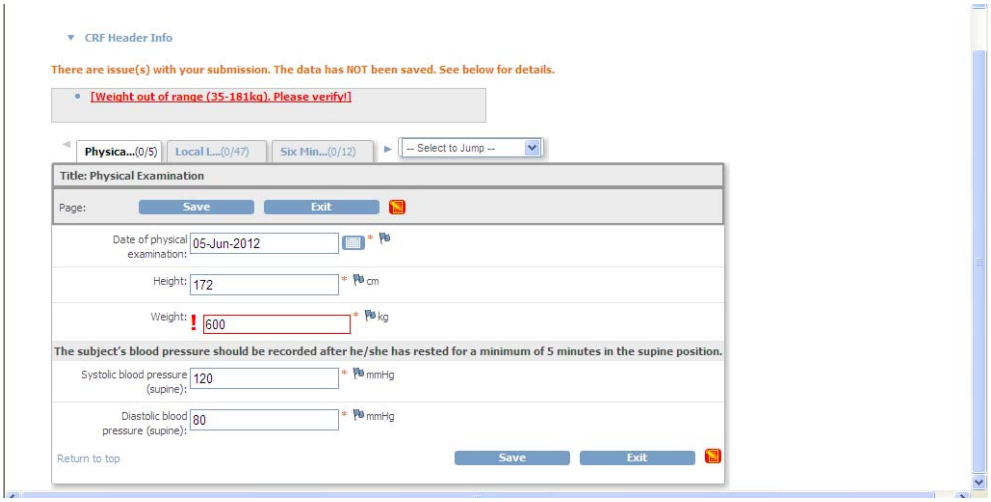
Enter your information about the weight (see below). The type will be default set to Annotation. When you click 'submit' the flag icon will turn to white (meaning 'not applicable').



7b. Example of a Failed Validation Check

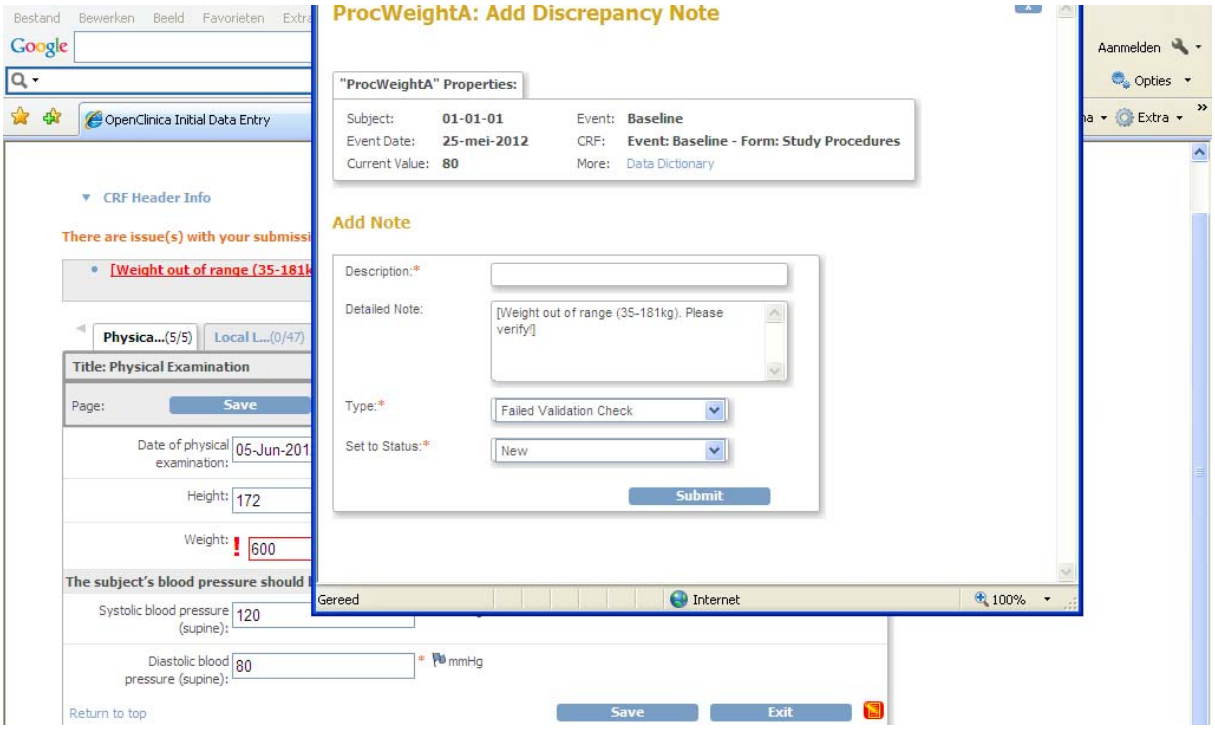
Depending on the setup of the study, automated validation checks may be executed on the entered data. An example of a failed validation check is shown below: if entered value for weight is too high and you click ‘save’, the message ”Weight out of range. Please verify” is shown.

The data has not been saved so far, since the system wants you to check the entered data first.

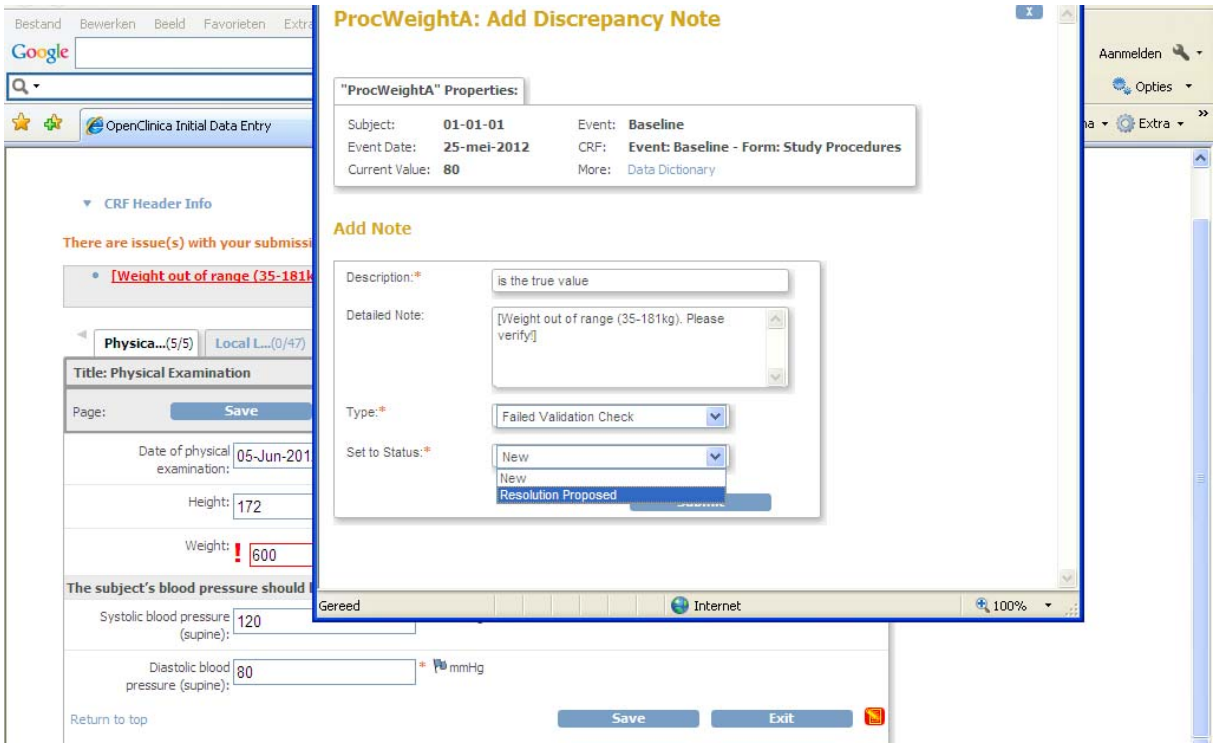

CRF Header Info
There are issue(s) with your submission. The data has NOT been saved. See below for details.
[Weight out of range (35-181kg). Please verify!]
Physica...(0/5)
Local I...(0/47)
Six Min...(0/12)
-- Select to Jump --
Title: Physical Examination
Page:
Save
Exit
Date of physical examination: 05-Jun-2012
Height: 172 cm
Weight: 600 kg
The subject's blood pressure should be recorded after he/she has rested for a minimum of 5 minutes in the supine position.
Systolic blood pressure (supine): 120 mmHg
Diastolic blood pressure (supine): 80 mmHg
Return to top
Save
Exit

You now have two options:
1. correct the value and then click save again
2. not correct the value and add a discrepancy note (see below)

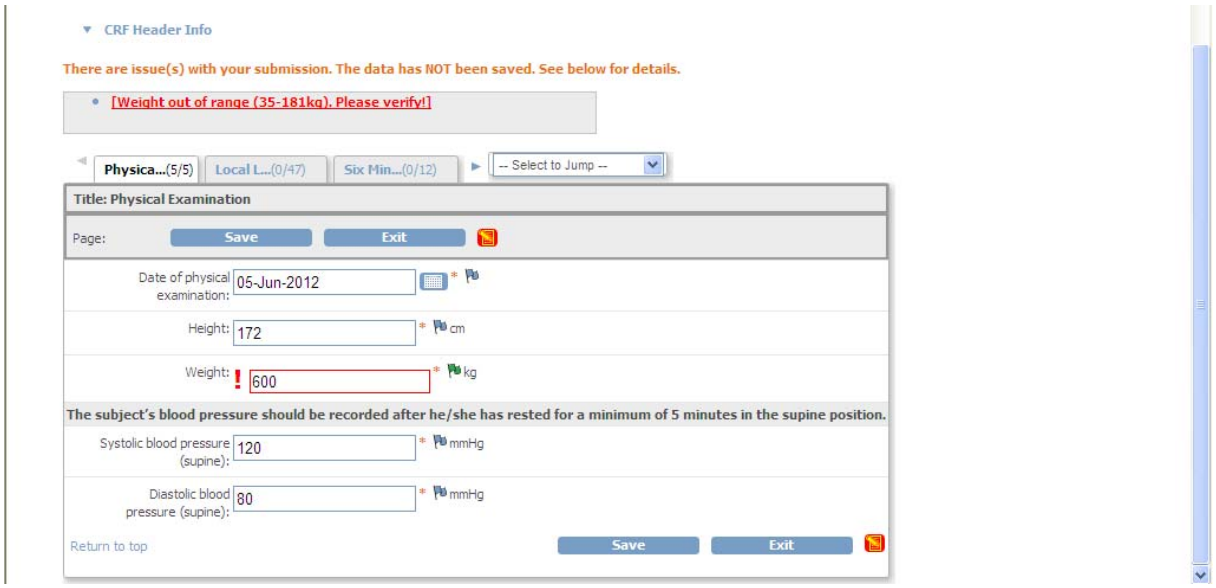
In order to be able to save the data that are out of range, you need to add a discrepancy note by clicking on the blue flag icon behind the weight data field. Then the following window opens:



Enter a note in the field, for example “is the true value” (see below). By default the type of the discrepancy note is ‘Failed Validation Check’. You should set the status of the note to ‘resolution proposed’ (see below)

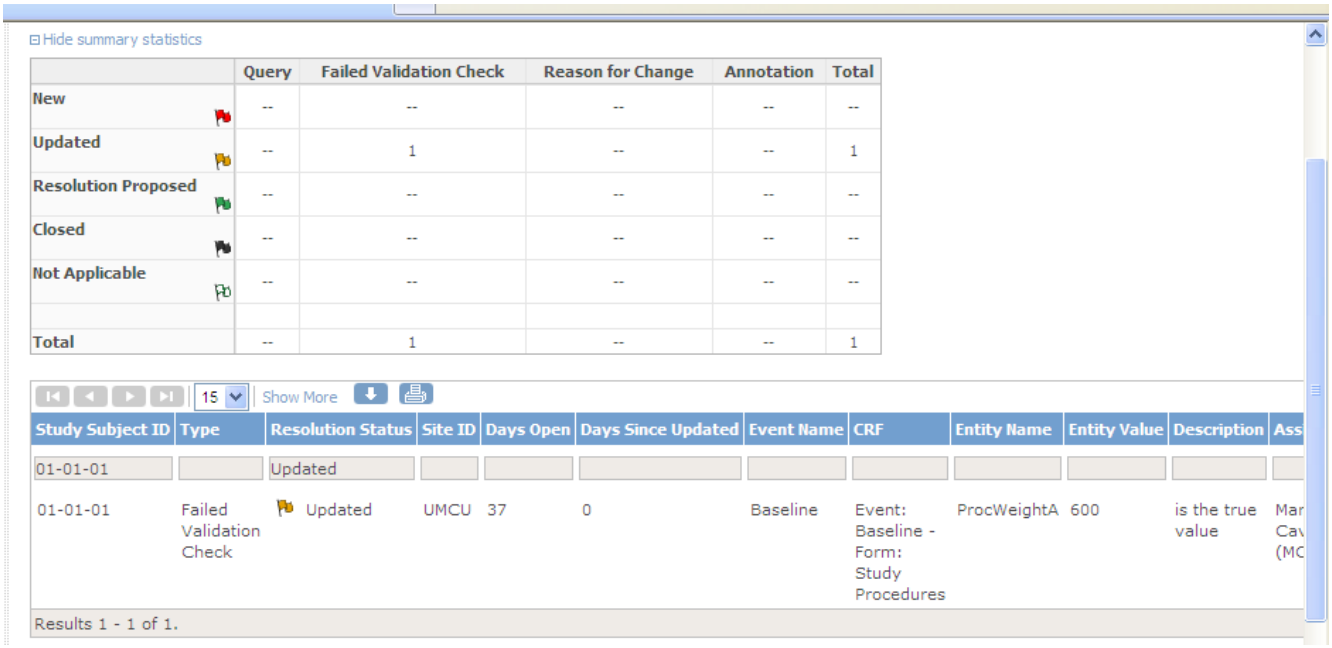


Then click “submit” and the flag will turn to green:



Now you can save the data in this section of the CRF.
NB: sometimes the flag will only turn to green after you clicked the save button.

The monitor / study team can respond to this discrepancy note. If they do so, the color of the flag will turn yellow (which means the note has been ‘Updated’; see below).



You have to respond to this updated discrepancy note again. For example after you have measured the weight again, you open the discrepancy note and click ‘Propose Resolution’ again. Add a description and detailed note and then click on ‘Submit & Exit’. The flag icon will turn to green again, meaning resolution proposed.

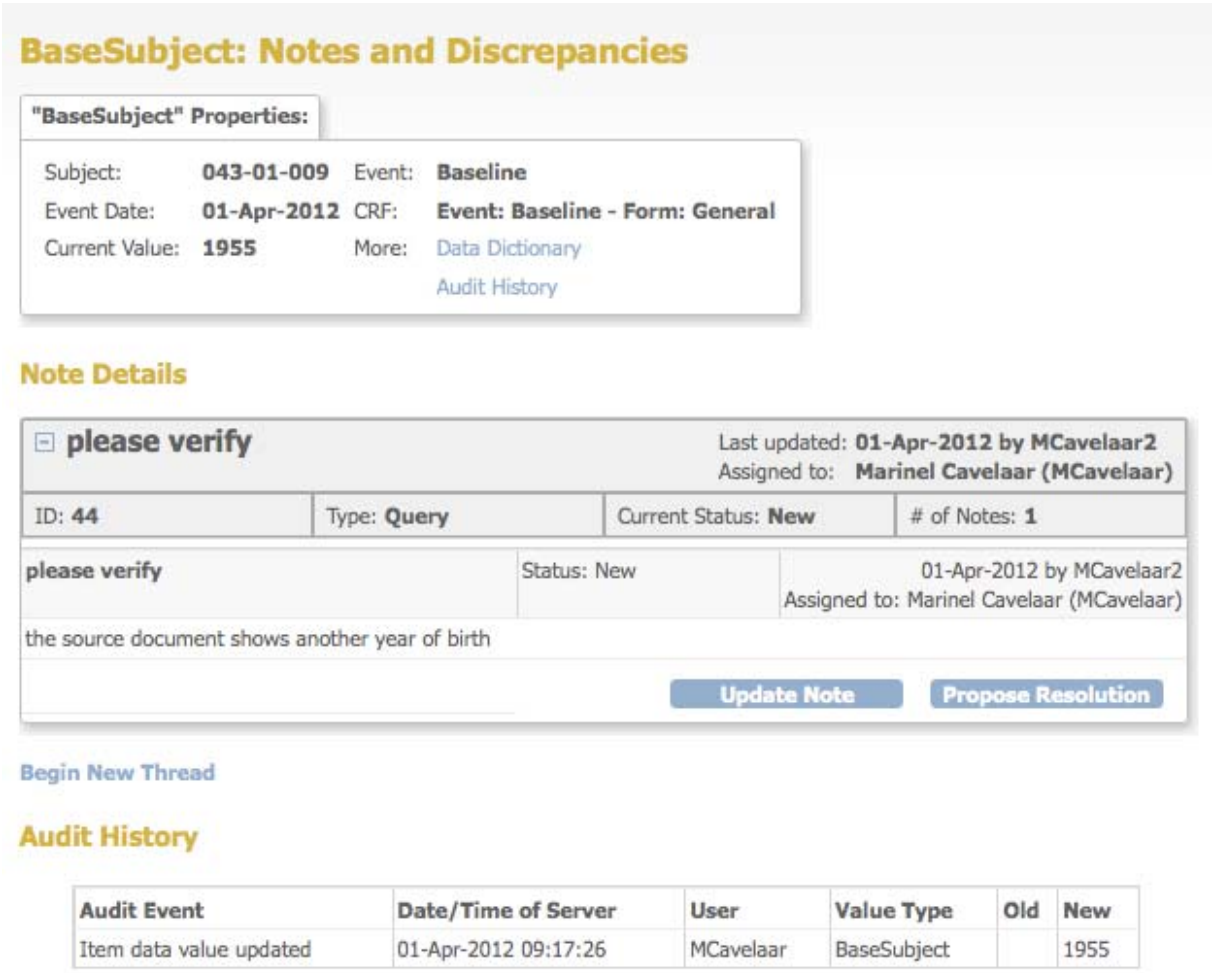
If the study team is satisfied with the resolution they will close the discrepancy note. The flag will turn black if a discrepancy note is closed.

Guideline regarding response to Discrepancy Notes with status New/Updated

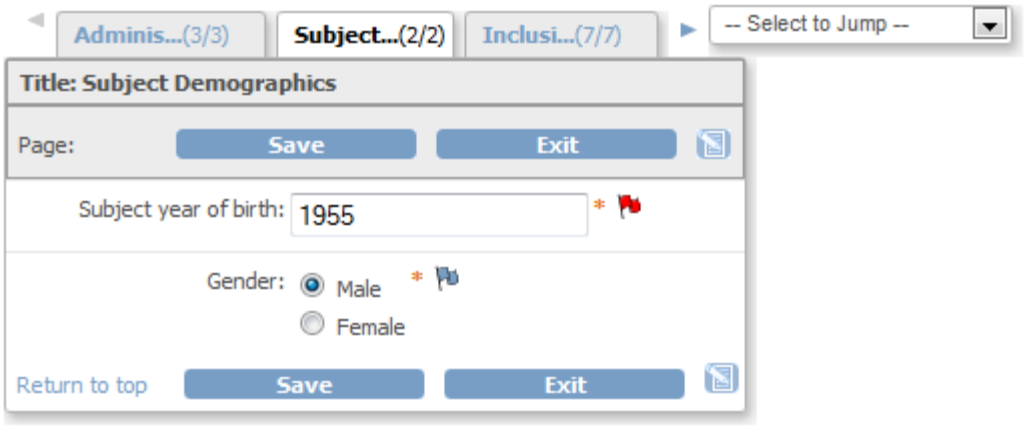
If you change a value based on a discrepancy note with status New (red flag) or Updated (yellow flag) or if you add a Discrepancy Note because of a Failed Validation Check, then set the status of this note to ‘Resolution Proposed’. In this way it is clear that there is no action expected from you as clinical research coordinator.

7c. Example of a Query

If the monitor / study team has questions about data, they can add a discrepancy note of type ‘Query’. This you will find again as a new discrepancy note in the list of discrepancies. Open the discrepancy note by clicking on the magnifier icon at the end of the line to see the details of the query.



In case that you want to edit the original data you need to go to the CRF via the Subject Matrix (as also explained on page 9/10). For more information you can first click on the 'View within record' icon . The CRF will now open in view mode and you can navigate to the right section to find the appropriate field.

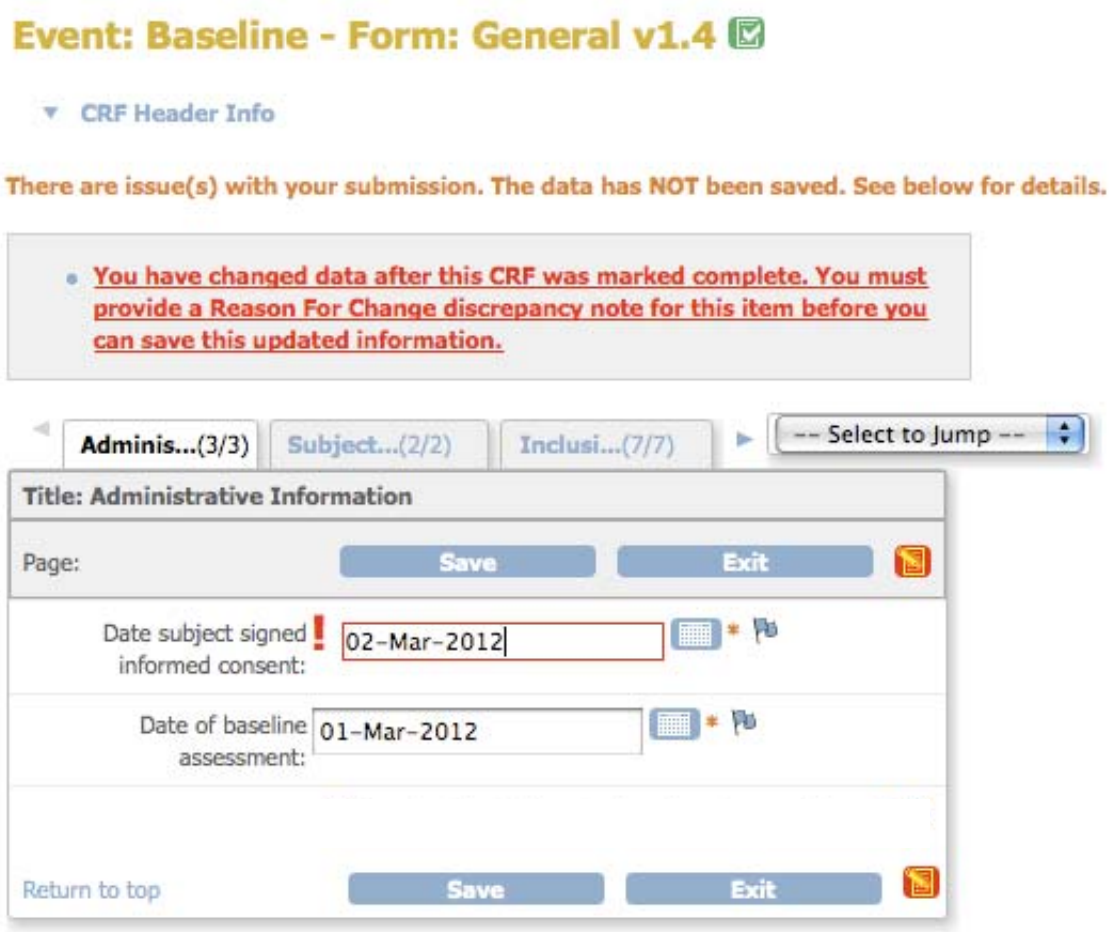


Change the data appropriately and afterwards click on the red flag to open the discrepancy for proposing a resolution (same as for 'Failed Validation Check', also see the Guideline for response to Discrepancy Notes with status New/Updated on page 18). Do not forget to save the form once more afterwards!

The monitor / study team will close the discrepancy note if the resolution is acceptable.

7d. Example of Reason for Change

If the CRF is marked as completed ( ) the system will ask you to give a reason for change in case you change the data.

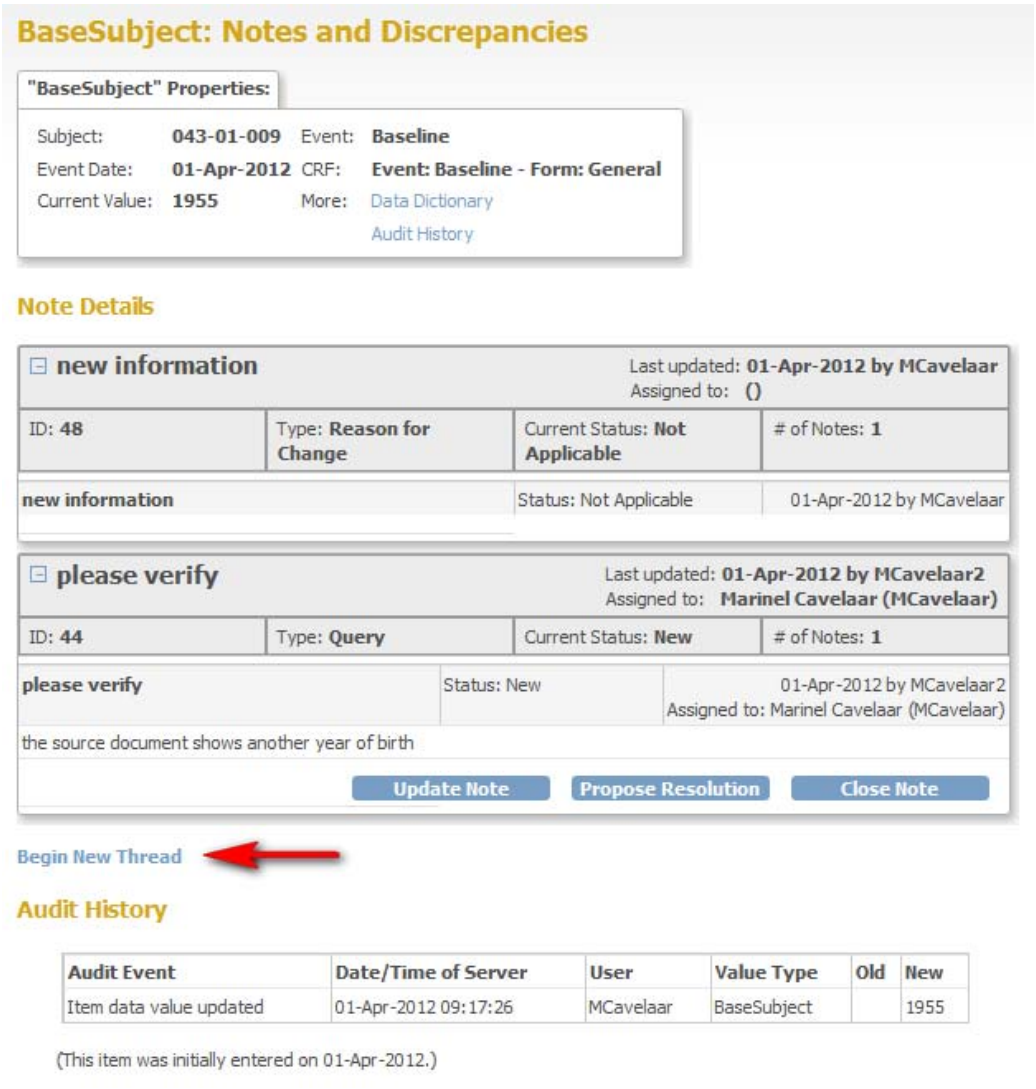

Event: Baseline - Form: General v1.4
CRF Header Info
There are issue(s) with your submission. The data has NOT been saved. See below for details.
You have changed data after this CRF was marked complete. You must provide a Reason For Change discrepancy note for this item before you can save this updated information.
Adminis...(3/3)
Subject...(2/2)
Inclusi...(7/7)
-- Select to Jump --
Title: Administrative Information
Page:
Save
Exit
Date subject signed informed consent:
02-Mar-2012
Date of baseline assessment:
01-Mar-2012
Return to top
Save
Exit

You can follow the same procedure as in case of a 'Annotation'. Click on the flag icon and provide a reason for change. Click Submit & Close and now you are able to save the data on the CRF. The color of the flag will change from blue to white (which means not applicable).

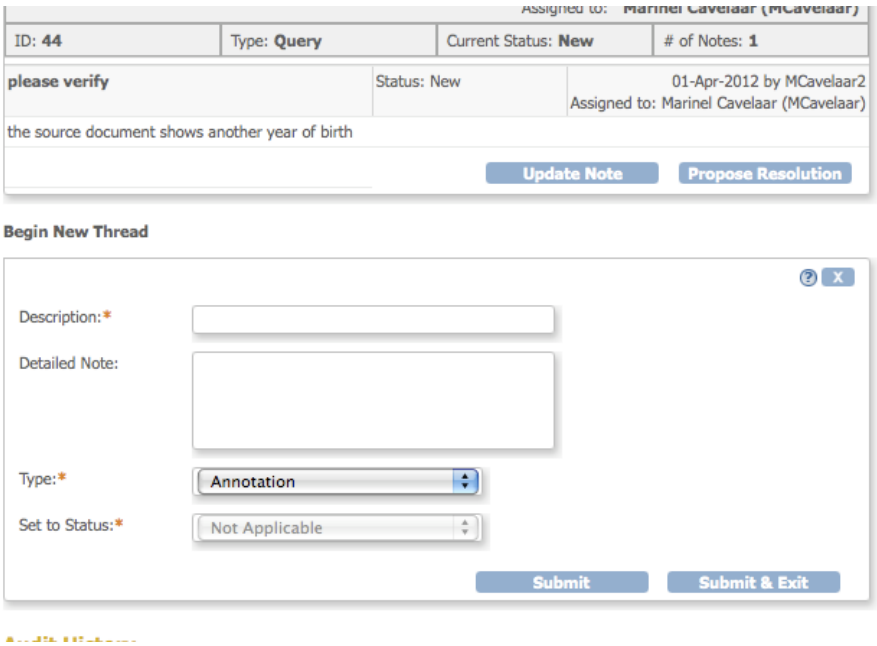
7e. More than one discrepancy note for a data field

One data field only has one flag icon. However, more discrepancies may be added.

For example, a validation check may have failed and, at a later stage, a reason for change may be required. In case you need to add an Annotation to this data field, a new thread needs to be opened. If you click on the flag icon the following screen will open:



Click on 'Begin New Thread' to add an Annotation. The next window will open:



You can enter a Description and Detailed Note. '*Type' will be 'Annotation' by default.*